

REMARKS

Claims 1-11 and 32-36 are now presented for examination. Claims 32-36 have been added. No new subject matter has been added. Support for the new claims can be found in paragraph 56 of the application.

Claims 1 and 11 are independent.

On page 2 of the Office Action, the Examiner has withdrawn Claims 7 and 8 from further consideration as being drawn to nonelected Species VII-XIII shown in FIGS. 2C-2D.

On page 2 of the Office Action, the Examiner requires correction of the Abstract of Disclosure so as not to exceed 150 words in length. Applicants have herein made such correction.

On page 3 of the Office Action, Claims 1 and 10 are rejected under 35 U.S.C. §102(b) as being anticipated by Fram, U.S. Patent No. 5,540,679. Applicants' respectfully traverse this rejection. In order for a reference to anticipate a claim under 35 U.S.C. §102(b), the reference must disclose each and every element of the claim. Claim 1 recites, in part, "*ablating* a desired tissue region while *maintaining the target pressure or volume* of the expandable membrane," (emphasis added). On Page 3 of the Office Action, the Examiner states that Fram '679 discloses such features at Col. 1, ln. 45-46; Col. 5, ln. 64-67, and Col. 6, ln. 4-6.

At Col.1, ln. 45-46, Fram discloses, "ablating electrically conductive pathways of a heart." At Col. 5, ln. 64-67, Fram discloses, "the balloon material is heat-set...so that the balloon material remains dimensionally stable when the fluid within the balloon boils." The heat-set characteristics of the balloon as disclosed refer to the capacity of the material to

withstand heat and the effects the heat may have on material features such as rigidity, pliability, etc., and doesn't relate to "maintaining the target pressure or volume." Finally, at Col. 6, ln. 4-6, Fram discloses, "When RF power supple is activated, the high electric field density...can induce localized boiling of fluids." As shown, the cited portions of the Fram reference fail to disclose or even relate to "ablating a desired tissue region while maintaining the target pressure or volume of the expandable membrane." Furthermore, although Fram '679 does disclose that "inflator 72 is used to inject fluid...until a desired pressure is obtained, as indicated by pressure gauge 74," (Col. 6, ln. 1-3), such disclosure does not provide for "maintaining the target pressure" during ablation, as claimed by Applicants. To the contrary, Fram specifically discloses that, "as the fluid 36 heats up, the boiling increases in intensity. The boiling *causes the pressure inside balloon 8 to increase.*" (Col. 6, ln. 6-8)(emphasis added). This increased pressure, Fram discloses, is used to make a correlating temperature measurement, as explained in Col. 6, ln. 8-12. Since the boiling causes pressure to increase, as explicitly stated, Fram cannot possibly anticipate "maintaining the target pressure or volume" as stated in Applicants' Claim 1, and actually discloses the exact opposite.

In addition, Claim 1 further recites, "controllably deflating the expandable membrane," which the Examiner states is disclosed by Fram at Col. 5, ln. 11-17. Although Fram does disclose providing "a conduit for fluid as the balloon is inflated and deflated," Fram makes no mention of "**controllably** deflating the expandable membrane" as stated in Claim 1, and further fails to disclose any deflation procedure whatsoever.

Therefore, as Fram fails to disclose, teach, or suggest the above-mentioned elements of Applicants' Claim 1, Claim 1 is believed to be in condition for allowance, and withdrawal of the

rejection under 35 U.S.C. §102(b) is respectfully requested. Moreover, Claim 10 is dependent from Claim 1, and is, therefore, also believed to be in condition for allowance.

On page 4 of the Office Action, Claim 2 is rejected under 35 U.S.C §103(a) as being unpatentable over Fram, ('679). Claim 2 is dependent from Claim 1, which, for the above-stated reasons, is believed to be allowable. As such, Claim 2 is also believed to be in condition for allowance.

On page 4 of the Office Action, Claims 3, 6, and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fram ('679) in view of Yamaguchi, U.S. Patent No. 5,433,740. Claims 3 and 6 are dependent from Claim 1, and are therefore believed to be in condition for allowance. Furthermore, Claim 11 recites, in part, "ablating the desired tissue region while maintaining the expandable membrane at the target pressure or volume; and controllably deflating the expandable membrane." As stated above, Fram fails to disclose, teach, or suggest either "maintaining the expandable membrane" or "controllably deflating" the device. Moreover, Yamaguchi fails to make any such reference to either of those stated limitations of Claim 1. Therefore, as Fram, either alone or in combination with Yamaguchi, fails to disclose, teach, or suggest the elements of Claim 1, Fram cannot, either alone or in combination with Yamaguchi, anticipate or render obvious Applicants' Claim 11. As such, Claim 11 is believed to be in condition for allowance, and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

On page 6 of the Office Action, Claims 4 and 5 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fram ('679) in view of Yamaguchi ('740) and further in view of

Edwards, U.S. Patent No. 6,258,087. Claims 4 and 5 depend from Claim 1, and are therefore believed to be in condition for allowance.

On page 7 of the Office Action, claim 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Fram ('679) in view of Joye, U.S. 2002/0045894. Claim 9 recites, in part, "wherein the step of ablating the desired tissue region is part of a cryoablation process." The Examiner indicates "it would have been obvious to one of ordinary skill in the art...to have introduced cryogenic fluid into the balloon of Fram in view of the teachings of Joye," (Office Action, Page 7). However, Fram discloses a device in which, "the balloon is inflated with the fluid, and the fluid is heated inside the balloon through use of the heating device," (Col. 1, ln. 55-57). Fram further discloses that the heating is sufficiently intense as to "induce localized boiling of fluid," (Col. 6, ln. 6). As the Fram device heats fluid to a point of boiling, the use of a cryogenic fluid would be inapposite to and achieve a result exactly counter to the one intended and taught by Fram, namely, to heat tissue. One of ordinary skill in the art would not inject a cryogenic fluid for subsequent boiling in order to heat tissue up to 100 degree Celsius, as stated in Col. 5, ln. 66 of the Fram reference. Such contrary uses exemplify the inappropriate combination of the Fram and Joye references, and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

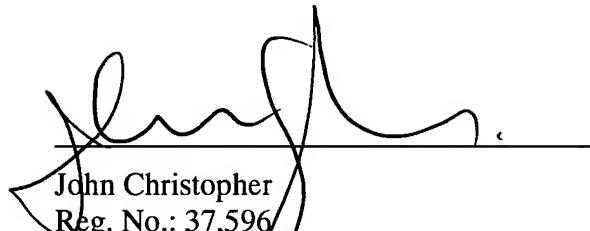
Claims 32-36 have been added, and are believed to be allowable as they depend directly or indirectly from allowable independent Claim 1.

For all of the above reasons, the claim objections are believed to have been overcome placing Claims 1-11 and 32-36 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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